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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,050	03/15/2004	David A. Cheresh	TSRI 651.7	2305

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EXAMINER	
VAKILI, ZOHREH	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
01/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,050	CHERESH ET AL.	
	Examiner	Art Unit	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 30-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,13-16 and 30-36* is/are rejected.

7)☒ Claim(s) *7-12,17-20 and 37-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 and 30-40 are presented for examination.

Applicant's response to the restriction/election requirement filed on September 14, 2007 is acknowledged. Accordingly, Applicant elects Group I (claims 1-20 and 30-40, SKI-606 species only) drawn to method of treating myocardial infarction without traverse.

The specie election requirement has been withdrawn so that examination has proceeded beyond SKI-606.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the prophylactic treatment of the disease. The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2nd 1400 (Fed. Cir. 1988) As to undue experimentation.

The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the relative skill of those in the art;
5) the amount of direction or guidance presented;
6) the presence or absence of working examples;
7) the quantity of experimentation necessary;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the art in the assessment of undue experimentation.

1) the nature of the invention; the invention is directed to a process for prophylactic treatment of myocardial infarction.

2) the breadth of the claims; the scope of the method claims include the prophylactic treatment of myocardial infarction.

3) the predictability or unpredictability of the art; the art does not enable a person of ordinary skill in the art to make and use the claimed invention without resorting to undue experimentation. The burden of enabling one skilled in the art for prophylactic treatment of myocardial infarction would be much greater than that enabling the treatment. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of prophylactic treatment of myocardial infarction. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for prophylactic treatment of myocardial infarction. No experimental evidence or mechanism of action for supporting prophylactic treatment of myocardial infarction using the specified actives by simply

administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the presently claimed method for prophylactic treatment of myocardial infarction. It is unpredictable for prophylaxis practice with a chemical administration as instantly claimed. The specification is viewed as lacking an adequate enablement of where myocardial infarction may be actually prophylactic treated.

4) the relative skill of those in the art; the relative skill of those in the art of pharmaceuticals is high.

5) the amount of direction or guidance presented; the specification and the example does not provide any guidance in terms of prophylactic treatment of myocardial infarction.

6) the presence or absence of working examples; no working examples are provided for prophylactic treatment of myocardial infarction, for example in a patient, in the specification. The applicant has not provided any competent evidence or disclosed any tests that are highly predictive for the preventative effects of the instant composition. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

7) the quantity of experimentation necessary; the quantity of experimentation would be an undue burden to one of ordinary skill in the art and amount to the trial and error type of experimentation. Thus, factors such as "sufficient working examples", "the level

of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant process claims. In view of the breadth of the claims, the chemical nature of the invention and unpredictability of prophylactic treatment of myocardial infarction, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

In consideration of each of factors 1-7, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 13-14, and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Feng et al. (US Patent 5,731,343).

Feng et al. teach methods of treating diseases including myocardial infarction using with the compound radicicol (see column 2, lines 37-41 and column 3, lines 54-60). Radicicol is disclosed as an inhibitor of the tyrosine kinase Src (see example 2). Feng et al. further teach that radicicol can be administered by intraperitoneal injection, intravenous injection, orally or parentally (see column 7, lines 34-40). The subject of the invention is preferably a human, however, it can be envisioned that any animal with an immunopathological disorder can be treated by the method of the invention (see col. 8, lines 66-67 and col.9, lines 1-2). Thus Feng et al. anticipate all of the instant claims.

Claims 1-3, 13-14, and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Das et al. (US Patent Application 2002/0123484).

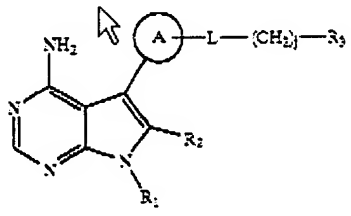
Das et al. teach methods of treating diseases including myocardial infarction using tyrosine kinase inhibitors (see paragraph [0164]). These compounds are disclosed as inhibitors of tyrosine kinases including Src kinases (see paragraph [0161]). Das et al. further teach that these compounds can be administered by intravenous injection, orally or parentally (see paragraph [0170]). Preferred subjects for treatment include animals, most preferably mammalian species such as humans, and domestic animals such as dogs, cats and the like, subject to protein tyrosine kinase-associated disorders (see paragraph [0176]). Thus Das et al. anticipate all of the instant claims.

Claims 1-3, 13-14, and 30-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Barrish et al. (US Patent 6,235,740).

Barrish et al. teach methods of treating diseases including myocardial infarction using tyrosine kinase inhibitors (see column 17, line 66 – column 18, line 6). These compounds are disclosed as inhibitors of tyrosine kinases including Src kinases (see column 17, lines 34-36). Barrish et al. further teach that these compounds can be administered by intravenous injection, orally or parentally (see column 19, lines 33-38). Preferred subjects for treatment include animals, most preferably mammalian species such as humans, and domestic animals such as dogs, cats and the like, subject to protein tyrosine kinase-associated disorders (see col. 20, lines 50-54). Thus Barrish et al. anticipate all of the instant claims.

Claims 1-5, 13-14, and 30-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al. (US Patent Application 2003/0187001).

Calderwood et al. teach methods of treating diseases including myocardial infarction using tyrosine kinase inhibitors having the structure shown (see paragraph 97).



These compounds are disclosed as inhibitors of tyrosine kinases including Src kinases (see paragraphs 53 and 111). Calderwood et al. further teach that these compounds

can be administered by intraperitoneal injection, intravenous injection, orally or parentally (see paragraph 126). Thus Calderwood et al. anticipate all of the instant claims.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-5, 13-16 and 30-36 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, 5, 6, 10-13, 21-25 and 27 of copending Application No. 10/535325. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The claims of the instant application and those of the copending application are identical.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 13-16 and 30-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 7-11, 19, 20, and 23-25 of copending Application No. 10/298,377. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 13-16 and 30-36 are generic to all that is recited in claims 3-5, 7-11, 19, 20, and 23-25 of copending Application No. 10/298,377. Both the claims in the instant application and that of the copending application recite methods of treating or preventing myocardial infarction by administering a Src kinase inhibitor, and preferably

SKI-606. Claims 1, 3-5, 7-11, 19, 20, and 23-25 of copending Application No. 10/298,377 fall entirely within the scope of claims 1-6, 13-16 and 30-36 or, in other words, claims 1-6, 13-16 and 30-36 are anticipated by claims 1, 3-5, 7-11, 19, 20, and 23-25 of copending Application No. 10/298,377.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 13-16 and 30-36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5,6, 7, 9-13, 21-25, and 27-28 of copending Application No. 10/535325. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the claims in the instant application and that of the copending application recite methods of treating or preventing myocardial infarction by administering a Src kinase inhibitor, and preferably SKI-606. The claims differ in the scope of Src kinase inhibitor. Claims 1-4 13-16 and 30-35 cannot be considered patentably distinct over claims 1-3, 5,6, 7, 9-13, 21-25, and 27-28 of copending Application No. 10/535325 when there is a specifically recited embodiment i.e., SKI-606 that would anticipate claims 1-5, 13-16 and 30-36. Alternatively, claims 1-5, 13-16 and 30-36 cannot be considered patentably distinct over claims 1-3, 5,6, 7, 9-13, 21-25, and 27-28 of copending Application No. 10/535325 when there is a specifically disclosed embodiment in the copending application that supports claims 1-3, 5,6, 7, 9-13, 21-25, and 27-28 of copending Application No. 10/535325 falls within the scope of claims 1-5, 13-16 and 30-36 herein because it would have been obvious to one having ordinary skill in the art to modify the

method of claims 1-3, 5,6, 7, 9-13, 21-25, and 27-28 by selecting a specifically disclosed embodiment that supports that claim, i.e., SKI-606. One having ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims 1-5, 13-16 and 30-36.

Claim Objections

Claims 7-12, 17- 20, and 37-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
1614

November 16, 2007

12/9/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER